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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kristin J. Godbey

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

12/12/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 09/854,824	<b>Applicant(s)</b> GODBEY ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, filed on 9 September 2008.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-22, and 29-39 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,780,047 ("Kamiya").

Kamiya discloses a device for delivering at least one active agent to a localized body surface (see col. 1, lines 4-12) comprising:

- the cold water-soluble carrier of instant claim 1 (see col. 2, lines 14-49);
- the cold water-soluble adhesive of instant claim 1 (see col. 4, line 36);
- the support layer of instant claim 1 (see col. 10, line 44);
- the nonwoven fabric of instant claim 2 (see col. 6, line 2);
- the monomers of instant claim 3 (see col. 4, line 12);
- the polyvinyl alcohol of instant claim 4 (see col. 3, lines 7-8);
- the gelatin of instant claim 5 (see col. 4, line 41);
- the polyhydric alcohol (sorbitol) of instant claim 7 (see col. 5, line 11);

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- the alkyl ether ethoxylate (phenylethyl alcohol) of instant claim 8 (see col. 7, line 35);
- the sorbitol of instant claim 9 (see col. 5, line 11);
- the pressure sensitive adhesive of instant claim 10 (see col. 10, lines 30-43);
- the cold water-soluble polymer of instant claim 11 (see col. 3, lines 7-8);
- the plasticizer (sorbitol) of instant claim 11 (see col. 5, line 11);
- the water-soluble monomer of instant claim 12 (see col. 4, line 12);
- the polysaccharide of instant claim 13 (see col. 3, line 24);
- the polymeric film of instant claim 14 (see col. 5, line 40);
- the cold water-soluble carrier of instant claim 15 (see col. 2, lines 14-49);
- the cold water-soluble adhesive of instant claim 15 (see col. 4, line 36);
- the support layer of instant claim 15 (see col. 10, line 44);
- the active agent effective for treatment of skin of instant claim 16 (see col. 1, line 7);
- the dye of instant claim 17 (see col. 7, line 54);
- the sodium monophosphate (sodium phosphate) of instant claim 18 (see col. 7, line 7);
- the appliqué (pigment) of instant claim 19 (see claim 11);
- the perfume of instant claim 20 (see claim 11);
- the deodorant (perfume) of instant claim 21 (see claim 11);
- the drug of instant claim 22 (see col. 7, line 16);
- the nonwoven fabric of instant claim 29 (see col. 6, line 2);

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- the monomers of instant claim 30 (see col. 4, line 12);
- the polyvinyl alcohol of instant claim 31 (see col. 3, lines 7-8);
- the monohydric alcohol (*e.g.* stearyl alcohol) of instant claim 32 (see col. 7, line 51);
- the alkyl ether ethoxylate (phenylethyl alcohol) of instant claim 33 (see col. 7, line 35);
- the sorbitol of instant claim 34 (see col. 5, line 11);
- the pressure sensitive adhesive of instant claim 35 (see col. 10, lines 30-43);
- the cold water-soluble polymer of instant claim 36 (see col. 3, lines 7-8);
- the plasticizer (sorbitol) of instant claim 36 (see col. 5, line 11);
- the water-soluble monomer of instant claim 37 (see col. 4, line 12);
- the polysaccharide of instant claim 38 (see col. 3, line 24);
- the polymeric film of instant claim 39 (see col. 5, line 40).

The processes claims 23-28 are not essential to a determination of patentability of the system disclosed in the claim. The patentability of product-by-process claims is based on the product itself. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,780,047 ("Kamiya") in view of U.S. Patent No. 5,028,435 ("Katz").

Kamiya teaches a device for delivering at least one active agent to a localized body surface (see above).

Kamiya explains that the disclosed device is beneficial because it, "...can exert excellent effects of relieving topical symptoms of a human body." See col. 2, lines 15-16.

The Kamiya reference differs from the instant case in that it does not teach the arabinogalactan of instant claim 6.

Katz, et. al. teach use of a protein and a carbohydrate in a transdermal system.

Katz, et. al disclose a transdermal delivery system comprising a backing having a matrix layer which incorporates a drug and a percutaneous enhancer for the drug. At least one of the drug and enhancer is contained within a plurality of polymeric particles dispersed throughout the matrix layer (see col. 3, lines 58-62). The particles may be formed using natural polymers such as arabinogalactan (see col. 7, lines 28-32).

Katz, et. al. explain that polymers such as arabinogalactan and gelatin are useful because they contribute to the stability of the transdermal drug delivery device, as well as to a long shelf life for the device (see col. 7, lines 14-19).

Thus, it would have been obvious for one of ordinary skill in the art at the time of the invention to add a protein, such as collagen, and a carbohydrate, such as arabinogalactan to a transdermal delivery device, as taught by Kamiya in view of Katz, et. al. Motivation to do so, as explained above, would come from increased stability and longer self life of the device.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed on 9 September 2008 have been fully considered but they are not persuasive.

### **35 USC 102**

Applicants argue that Kamiya does not disclose a construction in which a carrier is sandwiched between the adhesive and the support layer. See remarks, page 9.

At the outset, it should be noted that applicants are only claiming one layer, i.e. the support layer (see claim 1). In claim 1, the carrier and adhesive are not being claimed as individual layers that situated in a particular order, i.e. an adhesive layer attached to a carrier layer attached to a support layer.

As such, examiner respectfully submits that the prior art anticipates the instant application as claimed. For example, Kamiya discloses a mix of polymer, plasticizer, and adhesive (i.e. the carrier and adhesive of the instant application) attached to a

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water-soluble protective material and/or a highly peelable film (i.e. the support layer of the instant application - see col. 10, lines 30-43). The carrier of Kamiya (even at a molecular level) will have a first surface and a second surface. Thus, the Kamiya formulation will have a carrier with one surface attached to the adhesive and the other surface attached to the support layer.

\*

**35 USC 103**

Applicants argue that, "...Katz fails to teach or disclose a cold-water soluble carrier layer, cold-water soluble adhesive layer, and a support layer." See remarks, page 9.

Examiner respectfully submits that claim 1 of the instant application does not recite a distinct carrier layer or a distinct adhesive layer (see response to arguments addressing the 35 USC 102 rejection, above). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

\* \* \* \* \*

**Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1618

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615